

Appl. No. 10/730,567
Amdt. Dated: 03/16/2006
Reply to Office Action of December 19, 2005

lack of functioning of the secretory cells of the proximal small intestine, preclude the proper formation and or release of secretin. It is further postulated that this abnormal protein digestion as reflected by the low levels of pancreatic enzymes such as chymotrypsin, can be improved by the administration of secretin, CCK, VIP, other neuropeptides, peptides and/or digestive enzymes to thereby ameliorate the ~~symptomotologies~~ symptomatology of dysautonomic conditions. Indeed, as low measures of fecal chymotrypsin, for example, expresses an abnormality of protein digestion and/or pancreatic dysfunction, it is postulated that an improvement of protein digestion to promote normal growth and development of an individual suffering from a dysautonomic disorder or dysautonomic condition by the administration of secretin, CCK, VIP, other neuropeptides and/or peptides and/or digestive enzymes, can ameliorate the dysautonomic symptomatology.

Please replace paragraph [0048] with the following amended paragraph:

[0048] The following case studies support the above findings. Further, preferred methods for diagnosing and treating dysautonomic disorders and ~~dysautonomie~~ dysautonomic conditions in accordance with the invention are described. It is to be understood that these examples are set forth by way of illustration only, and nothing therein shall be taken as a limitation upon the overall scope of the invention.

AC
7/14/06
Please replace paragraph [0055]⁵³ with the following amended paragraph:

⁵³
[0055] A 6 year old male child previously diagnosed with Familial Dysautonomia presents with marked autonomic dysfunction, including a total inability to walk or talk. The child lacked fine motor movements, and underwent an autonomic crisis 5-7 times per day, which necessitated continuous skilled nursing, with life support equipment including a respirator in close proximity. The child was fed with a food pump, and had to have his bowel evacuated by hand due to the near total ~~anestization~~ anesthesiation of the small and large intestines. Fundal Plication was performed in order to deduce the incidence of reflux, and excessive drooling was continually

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present. The child was completely dependent upon his care givers, and was classified during his first year of life as having autistic qualities.

AC
7/14/06
Please replace paragraph [0056]⁵⁴ with the following amended paragraph:

[0056] The child was administered ongoing secretin infusions. A preferred secretin infusion process includes the initial step of prepping an arm of the individual with an IV injection of saline. A test dose of 1 U of, e.g., Secretin-Ferring is then administered to the individual. Approximately one minute after infusion, the ~~individual~~ individual is examined for signs of allergic reaction including rash, increased heart rate, and increase of blood pressure. If the individual does not display any signs of allergic reaction, the remaining units of Secretin-Ferring is administered to the individual in the manner of an IV push, which is then followed by a saline flush. Subsequently, the individual receives a 1-2 U/kg of body weight infusion of Secretin-Ferring via an IV push method approximately every 4 weeks for 8 months.

AC
7/14/06
Please replace paragraph [0057]⁵⁵ with the following amended paragraph:

[0057]⁵⁵ It is to be understood that any commercially available form of secretin may be used. Furthermore, treatment of a dysautonomic condition can be made by the administration of an effective amount of secretin, neuropeptide, CCK, VIP, peptides and or digestive enzymes through one of intravenous, transdermal, intranasal, small molecule or a combination thereof, or other suitable suitable methods of administration.

AC
7/14/06
Please replace paragraph [0065]⁶⁰ with the following amended paragraph:

[0065]⁶⁰ 4 children were administered secretin in the amount of 1 U/kg. Table 1 below demonstrates the changes observed where "BP" denotes is blood pressure and FC ~~denotes~~ denotes fecal chymotrypsin level. As shown in Table 1, a significant decrease in blood pressure

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was observed in each child immediately after the administration of secretin. Additionally, a flush similar to that of niacin sensitivity was observed in 3 children.

AC
7/14/06
Please replace paragraph [0068] with the following amended paragraph:

[0068] In summary, the results of the case studies described herein demonstrate that ~~dysautonomic~~ dysautonomic disorders may be treated with the ~~administration~~ administration of secretin, CCK, VIP, and other neuropeptides and peptides and/or digestive enzymes. Furthermore, the results indicate that the quantitative level or activity of pancreatic enzymes in a stool sample, such as fecal chymotrypsin, can be used to determine if an individual has, or can develop, one or more dysautonomic disorders or conditions. Further, pancreatic enzymes such as chymotrypsin can be used as biological markers to determine the efficacy of administering secretin, CCK, VIP, and other neuropeptides and peptides and/or digestive enzymes to an individual having a dysautonomic disorder or condition to thereby treat the individual. Indeed, the above case studies indicate that the administration of secretin, CCK, VIP, and other neuropeptides and peptides and/or digestive enzymes to such individuals having, for example, sub-normal to pathologic levels of fecal chymotrypsin, will result in the amelioration of symptomatology of such disorders.